REMARKS

Claims 54-64 and 67-76 are pending in the application. Claims 54, 60, 62, 67, and 69, have been amended. Support for the claim amendment regarding the harness providing 3 mm Hg compressive force is found at page 3, line 20 through page 4, line 3 and page 27, lines 1-8. No new matter is presented. Claims 55, 61, 70 and 74 have been canceled.

Claim Rejections Under 35 U.S.C. § 112

Claim 67 has been rejected under 35 U.S.C. § 112. The trade name Nitinol has been deleted, and replaced with nickel titanium alloy. Accordingly, the rejection under § 112 has been obviated.

Double Patenting

Claims 54-64 and 67-76 have been rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over co-pending U.S. Serial Nos. 10/693,577 and 10/314,696. A terminal disclaimer is being filed concurrently herewith to obviate the double patenting rejection.

Claim Rejections Under 35 U.S.C. § 103

Claims 54-64 and 67-76 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Jayaraman (U.S. Patent No. 6,360,749) in view of Lau et al. (U.S. Patent No. 6,517,570). Applicant respectfully traverses. Each of independent claims 54, 60, and 69 have been amended to recite a cardiac harness which "provides a continuous compressive force on the heart of less than 3 mm Hg throughout a cardiac cycle." Jayaraman teaches away from the claimed invention. Attention is drawn to FIGS. 7B and 7C of Jayaraman in which the band 27 is shown constricting the heart during diastole (FIG. 7C). Further, during systole, when the ventricle contracts, the band 27 of

Jayaraman squeezes the volume of the heart (column 13, lines 44-49). The amount of compression of band 27 is substantially higher as disclosed in Jayaraman and the intent is to compress the ventricles so that the band squeezes the volume of the heart both during systole and diastole. As the Examiner is probably aware, there can be 5 to 15 mm Hg pressure in the ventricles during diastole and up to 100 mm Hg pressure during systole. Jayaraman would have to generate substantial pressure with band 27 to compress the ventricles as shown in FIG. 7C and as disclosed in the specification. At column 11 of Jayaraman, lines 14-26, the band is described as being sutured onto the ventricle wall so that the ventricle wall is pulled closer together thus reducing the volume of the ventricle. Further, Jayaraman describes "an overlap of the wall tissue" is formed and is held in a physically constricted state. Thus, Jayaraman discloses a band designed to provide a compressive force on the heart that is orders of magnitude higher than 3 mm Hg set forth in the claims, which is in the range of the compressive force exerted on the heart by the native pericardium. Further, there is nothing in Lau et al., which discloses stents, to suggest the Jayaraman bands are to be designed with any less constrictive force. Accordingly, it is respectfully urged that the independent claims, as amended, and the claims that depend therefrom, are patentably distinguishable over Jayaraman in view of Lau et al.

In the Office action, the Examiner has argued that claim 61, for example, which describes the pressure exerted on the heart by the cardiac harness to be in the range of 3 to 4 mm Hg, is inherent in the combination of Jayaraman and Lau et al. The reasoning set forth by the Examiner is because the hinge elements of Lau et al. are identical to the claimed material. Applicant respectfully disagrees. As stated previously in this application, and co-pending applications having the same art rejections, Lau et al. relates to stents and stent graft material which is designed to hold open an artery and is substantially rigid in the expanded state. There is no teaching in Lau et al. to suggest that the stent is highly compliant as are the hinge elements set forth in the present application, and designed to provide a continuous pressure on the heart of less than 3 mm Hg. As the

Examiner is undoubtedly aware, in order to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). The Court of Appeals for the Federal Circuit has cautioned that inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. at 1269, 20 USPQ2d at 1749, quoting In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

As a final matter, it is believed that it is improper to base a rejection on inherency when the claims being rejected are on the grounds of obviousness. It is believed the Examiner is confusing anticipation by inherency, i.e., lack of novelty, with that of obviousness. The rejection of the present claims under § 103 is for that of obviousness, not anticipation, therefore reliance on inherency to form the basis of a claim rejection is misplaced. Obviousness is not inherent anticipation. Trintec Industries, Inc. v. Top-U.S.A. Corp., 295 F.3d, 1292, 1296, 63 U.S.P.Q.2d 1597, 1600 (Fed. Cir. 2002). Though anticipation is the epitome of obviousness, they are separate and distinct concepts. Jones v. Hardy, 727 F.2d 1524, 1529, 220 U.S.P.Q. 1021, 1025 (Fed. Cir. 1984). Accordingly, the rejection of claims 61 and 74 reciting 3-4 mm Hg as inherent in Lau et al., is an anticipation rejection, not an obviousness rejection. Similarly, the independent claims now all recite that the compressive force generated by the cardiac harness is less than 3 mm Hg, and it cannot be argued that this compressive force is found in Lau et al. stent art since the rejection is not being made on anticipation, but on obviousness grounds.

In conclusion, claims 54, 56-60, 62-69, 71-73, and 75-76 remain pending in the application. Reconsideration is requested. If a telephone conference would facilitate prosecution of the application, the undersigned can be reached at (310) 824-5555.

Respectfully submitted,

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